DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 6, 2014

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director Regulatory Affairs/U.S. Agent
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K141472
Trade/Device Name: Vantage Elan
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: August 20, 2014
Received: August 21, 2014

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141472

Device Name

MRT-2020; Vantage Elan

Indications for Use *(Describe)*

Vantage Elan systems are indicated for use as a diagnostic imaging modality that produces cross-sectional transaxial, coronal, sagittal, and oblique images that display anatomic structures of the head or body. Additionally, this system is capable of non-contrast enhanced imaging, such as MRA.
MRI (magnetic resonance imaging) images correspond to the spatial distribution of protons (hydrogen nuclei) that exhibit nuclear magnetic resonance (NMR). The NMR properties of body tissues and fluids are:

- Proton density (PD) (also called hydrogen density)
- Spin-lattice relaxation time (T1)
- Spin-spin relaxation time (T2)
- Flow dynamics
- Chemical Shift

Contrast agent use is restricted to the approved drug indications. When interpreted by a trained physician, these images yield information that can be useful in diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY AND EFFECTIVENESS

1. CLASSIFICATION and DEVICE NAME:

Classification Name:	**Magnetic Resonance Diagnostic Device**
Regulation Number:	**90-LNH (Per 21 CFR 892.1000)**
Trade Proprietary Name:	**Vantage Elan**
Model Number:	**MRT-2020**

2. ESTABLISHMENT REGISTRATION: 9614698

3. Toshiba Medical Systems Corporation (TMSC)

1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan

4. CONTACT PERSON, U.S AGENT and ADDRESS:

U.S. Agent Name:
Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, Ca. 92780
Tel. (714) 669-7808

5. MANUFACTURING SITE:

Toshiba Medical Systems Corporation (TMSC)
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan

6. DATE OF SUBMISSION:

May 30, 2014

7. DEVICE DESCRIPTION:

The Vantage Elan (Model MRT-2020) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Elan uses 1.4m short and 4.1 tons light weight magnet. It includes the Toshiba Pianissimo™Σ technology (scan noise reduction technology). The design of the gradient coil and the whole body coil of the Vantage Elan provides the maximum field of view of 55 x 55 x 50 cm. The Model MRT-2020/A1 is without secondary cooling system and the Model MRT-2020/A2 is with secondary cooling system. The Vantage Elan MRI System

is comparable to the current 1.5T EXCELART Vantage Titan MRI System (K120638), cleared Jun 1, 2012 with the following modifications.

6.1 SUMMARY OF HARDWARE CHANGES

a. Main magnet has been changed from OR76 to TN150.
b. Maximum power of RF amplifier has been decreased from 20kW to 12kW.
c. Maximum Gradient field strength has been changed from 34mT/m to 33mT/m.
d. Maximum Slew Rate of gradient field has been changed from 148mT/m/ms to 125mT/m/ms.
e. Patient aperture size has been changed from 71cm to 63cm.
f. Number of units has been reduced from 7 to 5.
g. Optical transmission of MR signals from gantry to main cabinet.

6.2 SUMMARY OF SOFTWARE CHANGES

a. SpineLine (automatic positioning assistance for spine)
b. 2D RMC (2D Real-time motion correction)
c. New operating system (Windows 7)
d. ECG, peripheral pulse, and respiratory gating waveforms are displayed on the LCD monitor of console.
e. Control for new hardware

8. SAFETY PARAMETERS

Item	Vantage Elan (subject device)	Vantage Titan K120638 (Predicate Device)	Notes
Static field strength	1.5T	1.5T	Same
Operational Modes	1st Operating Mode	1st Operating Mode	Same
i. Safety parameter display	SAR dB/dt	SAR dB/dt	Same
ii. Operating mode access requirements	Allows screen access to 1st level operating mode	Allows screen access to 1st level operating mode	Same
Maximum SAR	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33(2010))	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33(2002))	Change*
Maximum dB/dt	<1st operating mode specified in IEC 60601-2-33 (2010)	<1st operating mode specified in IEC 60601-2-33 (2002)	Change*

Item	Vantage Elan (subject device)	Vantage Titan K120638 (Predicate Device)	Notes
Potential emergency condition and means provided for shutdown	Shut down by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Shut down by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Same

***Note:** The difference between predicate and subject device is due to the conformance of the subject device to IEC 60601-2-33 (2010)

8. IMAGING PERFORMACE PARAMETERS

No change from the previous predicate submission (K120638).

9. INTENDED USE

Vantage Elan systems are indicated for use as a diagnostic imaging modality that produces cross-sectional transaxial, coronal, sagittal, and oblique images that display anatomic structures of the head or body. Additionally, this system is capable of non-contrast enhanced imaging, such as MRA.
MRI (magnetic resonance imaging) images correspond to the spatial distribution of protons (hydrogen nuclei) that exhibit nuclear magnetic resonance (NMR). The NMR properties of body tissues and fluids are:

- Proton density (PD) (also called hydrogen density)
- Spin-lattice relaxation time (T1)
- Spin-spin relaxation time (T2)
- Flow dynamics
- Chemical Shift

Contrast agent use is restricted to the approved drug indications. When interpreted by a trained physician, these images yield information that can be useful in diagnosis.

No changes to the previously cleared indication (K120638).

10. SUMMARY OF DESIGN CONTROL ACTIVITIES

Hazard analysis has been performed and documentation is included in this submission. The test methods used are the same as those submitted in the previously cleared submissions (K120638). A declaration of conformity with design controls is included in this submission.

12. SUBSTANTIAL EQUIVALENCE

This device is based upon the same technologies, materials and software as the predicate device. Risk activities were conducted in concurrence with established medical device development standards and guidance. Additionally, testing was done in accordance with applicable recognized consensus standards as listed below.

List of Applicable Standards

- IEC60601-1:2005
- IEC60601-1-2:2007
- IEC60601-1-8:2003,Amd.1:2006
- IEC60601-2-33:2010
- IEC60825-1: 2007
- IEC62304:2006
- IEC62366:2007
- NEMA MS-1:2008
- NEMA MS-2:2008
- NEMA MS-3:2008
- NEMA MS-4:2010
- NEMA MS-5:2010
- NEMA PS 3.1-20 (2011)

In addition to the performance testing stated above, clinical image validation was conducted using volunteers to verify image quality and functionality of the system. Based upon this information Toshiba believes that it has established substantial equivalence to this device and the predicate.